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30. **(Amended)** The tablet of claim 29 further comprising a delivery port drilled into the [said] membrane at a location proximate to the [said] first layer.

31. The tablet of claim 30 further comprising a drug overcoat applied onto the surface of the membrane.

Remarks

Claims 18-23, 25, 27-28, and 30 having been amended, the claims pending in the above-identified patent application are claims 18-31. Claims 18-23, 25, 27-28, and 30 have been amended to more clearly define Applicants' invention. Support for these amendments can be found, for example, in the claims as originally filed and at page 4, lines 12-14.

In amending the above claims, Applicants are not acquiescing to objections or rejections asserted by the Examiner. Applicants have amended the claims to further the prosecution of this application and retain the right to file divisional or continuing applications to claim any canceled subject matter.

No new matter has been added by these amendments. Reconsideration and withdrawal of the rejections in light of the preceding amendments and following remarks are respectfully requested.

Extension of Time

A petition for a three-month extension of time and the fee therefore accompanies this response.

The Rejection Under 35 U.S.C. §102(e)

Claims 18-31 were rejected under 35 U.S.C. §102(e) as allegedly anticipated by Hoover et al. (U.S. Patent No. 5,464,631). To the extent the rejection applies to claims 18-31 as amended, it is respectfully traversed.

Hoover et al. relate to a coated or encapsulated pharmaceutical that can be administered in a caplet-type dosage form (column 1, lines 10-12). Specifically, the invention relates to a tamper-resistant and tamper evident pharmaceutical capsule whereby a medicament in the form of a caplet is partially encapsulated with one-half of an empty gelatin capsule that is essentially tasteless and easy to swallow (Column 3, lines 20-25). The two-color appearance of the dosage form allows for brand recognition and aesthetic appearance (column 4, lines 37-39). Generally, the body portion of the capsule and the caplet are different colors so as to give the appearance of bi-colored capsule (column 5, lines 17-19). The caplet includes at least one pharmaceutical active agent and other materials, such as coloring agents, can be included in the caplet (column 5, lines 35-47). The gelatin capsule will also be colored with a pharmaceutically acceptable coloring or dye so that it has a color different from that of the caplet and thereby exhibits a two-color appearance (column 6, lines 21-24). The dosage form may also contain an additional coating that may include, for example, methyl cellulose (column 7, lines 39-42).

In contrast to Hoover et al., Applicants' claims are directed to a dosage form that includes, *inter alia*, a multi-layered tablet. The multi-layered tablet includes, for example, a first layer formulation containing a drug ingredient and a second layer containing a drug ingredient, one of the first or second layers also containing a first colorant, a third layer formulation containing a second colorant that is distinguishable from the first colorant or from no color and not containing any drug ingredient. The first, second and third layers are compressed into a capsule-shaped osmotic tablet having the first layer formulation located at one end of the capsule shaped osmotic tablet and the third layer formulation located at the other end of the capsule shaped osmotic tablet and the second layer located between the first layer formulation and the

second layer formulation such that the formulation orientation of the tablet can be determined by detecting the color at a spot location on a side of the tablet corresponding to one or another differently-colored formulation layer depending on the formulation orientation of the tablet and wherein the formulation orientation of the tablet is detected by a color detector directed at the spot location on the side of the tablet.

To anticipate a claim for a patent, a cited reference must contain all the elements of that claim. As pointed out by the Examiner in the current Office Action at page 5, line 3 of the Action, Hoover et al. do not disclose or suggest a multi-layered tablet wherein the layers are compressed into a capsule-shaped osmotic tablet form as claimed by Applicants. Thus, Hoover et al. do not anticipate Applicants' claims.

Withdrawal of the rejection under 35 U.S.C. §102(e) is respectfully requested.

The Rejection Under 35 U.S.C. §103(a)

Claims 18-31 were rejected under 35 U.S.C. §103(a), as obvious over Hoover et al., (U.S. Patent No. 5,464,631) in view of Wong et al., (U.S. Patent No. 5,785,994). To the extent the rejection applies to claims 18-31 as amended, it is respectfully traversed.

Hoover et al., described above, relate to a coated or encapsulated pharmaceutical that can be administered in a caplet-type dosage form. Specifically, the invention relates to a tamper-resistant and tamper evident pharmaceutical capsule whereby a medicament in the form of a caplet is partially encapsulated with one-half of an empty gelatin capsule that is essentially tasteless and easy to swallow. The two-color appearance of the dosage form allows for brand recognition and aesthetic appearance.

Wong et al., relate to a dosage form for time-varying patterns of drug delivery, and more particularly, the invention concerns a dosage form provided as an osmotic device means for the rate-programmed delivery of a drug in time-varying patterns to a drug recipient (column 1, lines 16-20). The dosage form may contain, for example, a first drug-free layer (column 5, lines 21-

23), a second drug-containing layer (column 9, lines 38-40), and a third or push layer (column 12, lines 40-41). Exit ports are typically drilled on the drug-free side or delay-layer side of the dosage form (column 17, lines 56-57).

Applicants respectfully traverse this rejection for a number of reasons. Establishment of a *prima facie* case of obviousness requires that the cited documents teach or suggest all of the limitations of the rejected claims. In addition, some suggestion or motivation must be provided to modify the documents to reach the claimed invention. Further, a document must be considered as a whole, including those portions of the document that teach away from the claimed invention.

Applicants respectfully submit that all of elements recited in claims 18-31 are not taught or suggested by Hoover et al. in view of Wong et al. Moreover, Applicants further submit that one of skill in the art would not be motivated to prepare a dosage form as recited by Applicants' claims.

As stated above, Hoover et al. fail to teach or suggest a multi-layered tablet wherein the layers are compressed into a capsule-shaped osmotic tablet form as claimed by Applicants. Moreover, Hoover et al. do not teach or suggest detecting formulation orientation of a dosage form by means of a color detector that is directed at a spot location on the side of the dosage form. As stated above, the two-color appearance of the dosage form taught by Hoover et al., merely allows for brand recognition and aesthetic appearance not for detecting the formulation orientation of the dosage form.

Wong et al. fail to supply that which is lacking from Hoover et al. Wong et al. do not teach the presence of any colorants in a dosage form. Moreover, Wong et al. do not teach or suggest detection of the formulation orientation of a dosage form by means of a color detector that is directed at a spot location on the side of the dosage form.

In short, the cited documents, either alone or in combination, fail to teach, suggest, or motivate on of skill in the art to provide the dosage forms and methods as claimed by Applicants. For the above reasons, Applicants respectfully submit that the invention recited in claims 18-31

are patentable over Hoover et al. in view of Wong et al. Accordingly, reconsideration and withdrawal of the rejection under 35 U.S.C. §103(a) are respectfully requested.

Conclusion

In light of the remarks presented herein, it is respectfully submitted that pending claims 18-31 are in condition for allowance and notification to that effect is respectfully requested. The Examiner is invited to contact Applicants' Representative at the below-listed telephone number if it is believed that prosecution of this application may be assisted thereby.

CERTIFICATE UNDER 37 C.F.R. 1.8:

The undersigned hereby certifies that this paper is being deposited in the United States Postal Service, as first class mail, in an envelope addressed to: Assistant Commissioner for Patents, Washington, D.C. 20231, on this 6th day of December 2000.

Katrina M. Ghafghaichi
Katrina Ghafghaichi

Respectfully Submitted,

ALZA Corporation
1900 Charleston Road
Mountain View, CA 94043
(650) 564-5000

06 DEC 2000
Date

By: Paul B. Simboli
Paul B. Simboli
Reg. No. 38,616
Direct Dial: (650) 564-7840